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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,264	10/27/2003	Geoffrey A. Russell	112455-145568	2808

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EXAMINER

MALLARI, PATRICIA C

ART UNIT PAPER NUMBER

3735

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/694,264

Applicant(s)

RUSSELL ET AL.

Examiner

Patricia C. Mallari

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,26-32 and 34-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,26-32,34-36 and 38-45 is/are allowed.
- 6) ☒ Claim(s) 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/15/06 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 37 is under 35 U.S.C. 102(b) as anticipated by US Patent No. 5,820,622 to Gross. Gross teaches a method of comprising providing an analyte sensing element 52 having an indicating electrode 23,55 adapted to indicate an analyte concentration in a fluid in contact with the indicating electrode. The exterior surface of the analyte sensing element 23, 55 is covered by an absorbent layer 28, wherein a perfluorinated ion-exchange membrane such as Nafion® is an absorbent material (figs. 1 & 8; col. 15, lines 15-40; col. 17, lines 48-61 of Gross; see col. 2, lines 48-52 of US Patent No. 5,181,995 to Kummer for teaching of perfluorinated ion exchange material such as

Nafion® being an absorbent material). Since Nafion® is shown to be an absorbent material and permeable to glucose, water, oxygen and hydrogen peroxide (col. 15, lines 23-27 of Gross), it is clear that the absorbent layer further allows body fluid to be in contact with the indicating electrode upon introduction of the covered analyte sensing element into soft tissue of an animal body, thereby enabling an analyte concentration in the body fluid of the animal to be indicated (col. 15, line 27-col. 16, line 3; col. 17, line 64-col. 18, line 51 of Gross).

Response to Arguments

Applicant's arguments, see pp.7-8, filed 5/15/06, with respect to the allowability of claims 1 and 32 and the reference McAllister have been fully considered and are persuasive. The rejection of the claims has been withdrawn.

Allowable Subject Matter

Claims 1, 26-32, 34-36, 38-45 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: The prior art of record fails to teach or fairly suggest a method of measuring an analyte concentration in body fluid wherein an analyte sensing element having an indicating electrode covered by an absorbent layer forming an exterior surface of the analyte sensing element is provided and the analyte sensing element is removed from the animal body before the analyte sensing element is activated, in combination with all of the other limitations of the claims. US Patent No. 6,561,989 to Whitson teaches a

method or measuring an analyte concentration in body fluid in an animal body wherein the analyte sensing element is removed before the blood glucose monitoring system measures the signal produced by the reaction to determine the blood glucose concentration (col. 4, lines 5-14 of Whitson). However, the system is activated before insertion of the sensing element into the body (col. 3, lines 62-65 of Whitson) and the sensing element lacks an absorbent or spreading layer forming an exterior surface of the analyte sensing element.

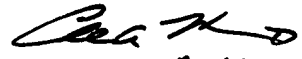
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Patricia Mallari
Patent Examiner
Art Unit 3735


Charles A. Marmor, II
SPE, Art Unit 3735